K031442

AUG 13 2003

MEDICAL DEVICE TECHNOLOGIES INC

3600 SW 47th Avenue
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662

510(k) SUMMARY

APPLICANT:	Medical Device Technologies, Inc. 3600 SW 47th Avenue Gainesville, FL 32608
CONTACT:	Karl Swartz Quality Assurance Manager
TELEPHONE:	(352)338-0440 fax (352)338-0662
TRADE NAMES:	PBN Guidewires
COMMON NAME:	Guidewires
CLASSIFICATION NAME:	Wire, Guide, Catheter, CFR 870.1330
PRODUCT CODE:	DQX
PANEL:	Cardiovascular

SUBSTANTIAL EQUIVALENCE:

Company Name	Product Name	510(k) No.
Microvenia Corporation	Guidewires	K991898

DESCRIPTION OF DEVICE:

The PBN Guidewires are made from a stainless steel or nitinol core wire surrounded by a stainless steel or tungsten spring. The PBN Guidewires will be provided uncoated, hydrophilic coated, or PTFE coated. The PBN Guidewires will be provided in the following diameters and lengths: .018 in. and .020 in. diameter, and 40 cm to 300 cm in length.

INDICATIONS FOR USE:

The PBN Guidewires are intended for use to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.

FUNCTIONAL & SAFETY TESTING:

The PBN guidewires were subjected to tensile strength, torque strength, torqueability, tip flexibility, and coating adherence/integrity tests. The results of the testing indicated that they are comparable to the predicate device.

K031442

MEDICAL DEVICE TECHNOLOGIES INC

`600 SW 47th Avenue
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662

TECHNICAL COMPARISON:

The following attributes of the PBN guidewire were examined and found to be comparable to the predicate device:

1. Intended size
2. Length
3. Distal end configuration
4. Intended anatomical location of distal end
5. Proximal end configuration
6. Materials
7. Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 3 2003

Medical Device Technologies, Inc.
c/o Mr. Karl Swartz
3600 S. W. 47th Avenue
Gainesville, FL 32608

Re: K031442
PBN Guidewires
Regulation Number: 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: May 2, 2003
Received: May 19, 2003

Dear Mr. Swartz:

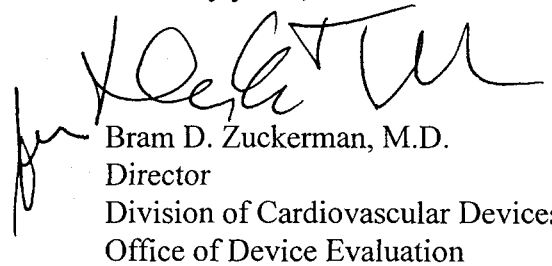
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MEDICAL DEVICE TECHNOLOGIES INC

3600 SW 47th Avenue
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662

510(k) Number (if known): K031442

Device Name: PBN Guidewires

Indications for Use:

The PBN Guidewires are intended for use to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031442